



Defendant's defective hip implant component known as the ProFemur Modular Neck, PHAO1252 and Conserve Cup Plus Cup (the "Defective Device" or "the Product").

2. The Product was surgically implanted in Plaintiff Beverly Miller's right hip on October 20, 2008, at Salem Hospital, Salem, OR by orthopedic surgeon Hal S. Boyd, M.D.

### **PARTIES**

3. Plaintiffs BEVERLY J. MILLER and DWYN E. MILLER, are citizens and residents of Salem, Marion County, Oregon. They are married to one another and were married at all times relevant to this action.

4. Defendant Wright Medical Technology, Inc. (hereinafter "Wright Technology" or "WMT") is a corporation organized under laws of the State of Delaware, with its principal place of business located in Memphis, Tennessee, and as such is a citizen of both the State of Tennessee and the State of Delaware. Defendant Wright Technology is registered to do business in the State of Oregon and did business in the State of Oregon, including in Marion County.

5. Defendant Wright Medical Group, Inc. (hereinafter "Wright Group" or "WMG") is a corporation organized under the laws of the State of Delaware, with its headquarters and principal place of business located in Memphis, Tennessee, and as such is a citizen of both the State of Tennessee and the State of Delaware.

6. Defendant Wright Medical Technology is a wholly owned subsidiary of Defendant Wright Medical Group. They are sometimes referred to collectively as the "Wright Medical."

7. At all times relevant hereto, the Wright Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing and/or

introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous prosthetic orthopedic products, including the Product, to members of the general public throughout the United States, including within the State of Oregon, and including to Plaintiff Mrs. Miller's implanting physician, or to his practice group or to the hospital where the implantation surgery occurred, and ultimately to Mrs. Miller.

8. The Wright Defendants were also involved in the business of monitoring and reporting adverse events concerning the Product, and the decision process and response of Defendants, if any, related to these adverse events.

9. In 2014, the Wright Medical OrthoRecon operating segment was sold by Wright Medical Group to a Shanghai entity known as MicroPort Scientific Corporation for approximately \$285 million. This sale included the ProFemur product line and its manufacturing facilities in Arlington, Tennessee.

### **JURISDICTION AND VENUE**

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and Defendants, and because Plaintiffs allege an amount in controversy in excess of \$75,000, exclusive of interest and costs.

11. The Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in the State of Oregon. At all relevant times, Wright Defendants transacted, solicited, and conducted business in Oregon through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Oregon.

12. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) because a substantial portion of the wrongful acts upon which this lawsuit is based occurred in this District. Venue is also proper pursuant to 28 U.S.C. § 1391(c) because Defendants are all corporations that have substantial, systematic, and continuous contacts in the District of Oregon and are all subject to personal jurisdiction in this District.

### **FACTUAL ALLEGATIONS**

#### **I. BEVERLY J. MILLER and DWYN E. MILLER**

13. On or about October 20, 2008, Beverly J. Miller underwent a total hip arthroplasty on her right hip due to osteoarthritis with insertion of the Wright ProFemur Modular Neck, PHAO1252 and Conserve metal acetabular cup. The surgical procedure was performed by Dr. Hal S. Boyd, M.D. at Salem Hospital in Salem, OR.

14. On or about April 16, 2019, Mrs. Miller underwent an invasive revision surgery performed by David Thorsett, M.D. at Legacy Silverton Medical Center in Silverton, Oregon. Intraoperative findings revealed a reaction to metal debris and Mrs. Miller was revised to a polyethylene liner.

15. As a result of the Defective Device, Plaintiffs' well-being has suffered, and will continue to suffer. Mrs. Miller and her husband, Dwyn E. Miller, have expended and will continue to expend money for her care, and expect to continue to suffer these losses and damages due to her ongoing pain, debilitation, and significant emotional distress.

16. Spouse Plaintiff Dwyn E. Miller has lost the society and love and affection of his beloved spouse.

## **II. BACKGROUND ON ARTIFICIAL HIPS AND HIP REPLACEMENT DEVICES**

17. The human hip joint consists of two parts: a ball and a socket. A portion of the pelvic bone forms a cup-shaped socket; the ball at the top of the thigh bone fits into it. The ball is surrounded with cartilage which, in a healthy hip joint, allows the ball to move smoothly within the socket. Conditions such as osteoarthritis and avascular necrosis can cause degeneration of the hip joint such that hip replacement is required. A hip implant is designed to replicate the human anatomy—that is, the relatively simple ball and socket structure of the human hip joint. Total hip replacement surgery involves implanting an artificial ball and socket into the patient.

18. The artificial hip implantation process requires a surgeon to insert a metal cup with a smooth lining into the patient's diseased pelvic socket. The lining serves the same purpose as natural cartilage: allowing for smooth movement of the ball portion of the thigh bone. The diseased or degenerated ball part of the thigh bone is then removed and replaced by a metal or sometimes ceramic ball mounted onto a thin metal stem. The metal stem is then fit into the thigh bone. Finally, the ball is placed securely into the pelvic socket that has been fitted with the artificial metal cup, where it should move easily, without friction or pain to the patient.

19. Total hip replacement is most commonly used to treat joint failure caused by osteoarthritis. Other indications include rheumatoid arthritis, avascular necrosis, traumatic arthritis, protrusion acetabuli, certain hip fractures, benign and malignant bone tumors, arthritis associated with Paget's disease of the bone, ankylosing spondylitis and juvenile rheumatoid arthritis. The aims of the procedure are pain relief and improvement

in hip function. Hip replacement is usually considered only once other therapies, such as pain medications, have failed.

20. Total hip arthroplasty (“THA”), or total hip replacement, is a common medical procedure performed on more than 420,000 patients in the U.S. each year. It is designed to help relieve pain and improve joint function in people with severe hip degeneration due to arthritis or trauma. Traditional devices to replace degenerative hips utilize implantable metal or ceramic heads fitting into a modular metal-backed polyethylene bearing. One concern that historically plagues successful THAs is the wear of the bearing. As the THA becomes more common among younger patients who want to maintain a physically active lifestyle, alternative bearing surfaces such as cross-linked polyethylene, ceramic-on-ceramic and metal-on-metal have been developed to address the issue of wear.

### **III. THE CONSERVE® SYSTEM**

21. The Wright Medical CONSERVE® Hip System has a different and defective design, one that puts a larger "big femoral head" metal ball directly in contact with a metal acetabular monoblock cup when most other hip replacements use a modular polyethylene or plastic acetabular cup or a polyethylene or plastic liner in the acetabular cup. By using a metal acetabular cup and a large metal femoral ball, the Wright Total Hip System creates greater torque and forces metal to rub against metal with the full weight and pressure of the human body.

22. Despite its unorthodox design, Defendants did not properly test the CONSERVE® Hip System for safety, efficacy and durability. Other metal-on-metal (hereinafter "MOM") prosthetic hip device manufacturers carefully screen, select and train orthopedic surgeons on proper implant procedures for their respective devices. However,

Defendants aggressively marketed, promoted and encouraged orthopedic surgeons in the U.S. to use the CONSERVE® System without screening, selecting, or training the surgeons on how to implant the CONSERVE® System.

#### **IV. WRIGHT PROFEMUR MODULAR NECK, PHAC1254**

23. The ProFemur Modular Neck, PHAO1252, is a component of a total hip replacement system used in THA surgeries. The device is part of a modular hip system, which has been associated with numerous complications including corrosion, disassembly, pseudotumors and, most notably, fractures of the modular neck.<sup>1</sup> Wright Medical originally manufactured the ProFemur device using a titanium alloy.

24. In December 1999, the WRIGHT acquired a European manufacturer of artificial hip devices known as Cremascoli Ortho ("Cremascoli"), which had designed and manufactured artificial hips with a modular neck component since approximately 1985.

25. Sometime after acquisition of Cremascoli, the WRIGHT re-branded the Cremascoli artificial hip modular neck product line, and a compatible artificial hip stem, as the PROFEMUR® System.

26. Through the Section 510(k) Premarket Notification Process, on December 13, 2000, WRIGHT received permission from the United States Food and Drug Administration (FDA) to distribute in the United States its first modular neck and stem artificial hip: the PROFEMUR® System.

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<sup>1</sup> Menci re, M.-L., et al. Fracture of the cobalt-chromium modular femoral neck component in total hip arthroplasty. *Orthopaedics & Traumatology: Surgery & Research* 100 (2014) 565-568, incorporated by reference herein.

27. The Wright Total Hip System devices the FDA permitted the Defendants to distribute via the 510(k) process included a modular neck component that had been designed and, since approximately 1985, had been distributed in Europe by Cremascoli.

28. The FDA never considered and approved the safety of the PROFEMUR® System, but instead concluded only that the PROFEMUR® System was substantially equivalent to an already legally marketed device, i.e., the Cremascoli modular neck device.

29. Sometime after December 13, 2000, WRIGHT began to manufacture, label and, both directly and indirectly, market, promote, distribute and sell in the United States the PROFEMUR® System and its components, including the Neck, Head and Cup components.

30. The PROFEMUR® Necks that were distributed after December 13, 2000, and before August 25, 2009, were all made of a titanium-aluminum-vanadium alloy known as Ti6Al4V.

31. In the year 2000, and in all years thereafter to the present, Ti6Al4V was an alloy generally available for use in manufacturing implantable medical devices.

32. On August 25, 2009, pursuant to a subsequent Section 510(k) Premarket Notification (No. K091423), the FDA permitted Wright to distribute and market a Profemur device manufactured from cobalt chrome alloy instead of Ti6Al4V, concluding - without assessing the safety of the device - only that the cobalt chrome alloy device is "substantially equivalent" to the Ti6Al4V device.

33. The Wright Medical Profemur modular necks, as promoted, marketed, distributed and sold in the United States after December 13, 2000, for use with various Wright Medical hip systems, were manufactured in twelve models or styles, six of those twelve were generally identified by Wright as "short" necks (i.e., Catalog #s PHA0-1202, PHA0-1212, PHA0-1222,



PHA0-1232, PHA0-1242, and PHA0-1252), and six identified by Wright as "long" necks (i.e., Catalog #s PHA0-1204, PHA0-1214, PHA0-1224, PHA0-1234, PHA0-1244, and PHA0-1254).

34. Since 1985, Defendants, , directly or through its parent corporation, subsidiaries or affiliates, Wright Medical Group, Inc., Wright Medical Europe, S.A., Cremascoli Ortho, Wright Cremascoli Ortho, and others, designed, manufactured, labeled, marketed, promoted, distributed, and sold in the United States the artificial hips with modular components.

35. In various marketing and promotional material published and distributed by WRIGHT and distributors, provided to surgeons, patients and the general public, including Plaintiff's implanting surgeon, Defendants made the following representations, statements, claims and guarantees about its PROFEMUR® Necks:

The modular neck used with the Profemur Hip has been employed by Wright Cremascoli for over 15 years. The necks were designed in 1985 and have been successfully implanted in over 50,000 patients requiring both primary and revision hip procedures. The necks are used in other Wright Cremascoli hip systems besides the Profemur Hip. None of the necks has experienced a clinical failure since their inception. [emphasis added]

and,

The modular neck system, designed by Cremascoli in 1985 (U.S. Patent #4,957,510), has now been successfully implanted in over 50,000 patients requiring both primary and revision hip arthroplasty. Extensive laboratory tests have proven that the coupling between the modular neck and femoral implant guarantees:

- Structural reliability
- Absence of significant micromovement
- Absence of fretting corrosion [emphasis added]

These excellent characteristics are obtained due to the particular geometry of the coupling. The base of the neck and the neck housing in the femoral implant have a patented oblong, conical profile which allows excellent stability under stress and the absence of all significant movement. The surface of the modular neck is finely machined to create spiral grooving.

The crest of these grooves deforms when the neck is inserted into the neck housing ensuring contact and elimination of micromotion.

[Wright Medical Technical Monograph MH688-102 2004]

36. The above quoted statement by WRIGHT Defendants, that it, “guaranteed . . . absence of fretting corrosion,” with its PROFEMUR® modular necks was false at the time it was first made.

37. WRIGHT Defendants have never corrected or recanted the above quoted statement that it, “guaranteed . . . absence of fretting corrosion,” with its PROFEMUR® modular necks.

38. Testing done by WRIGHT Defendants prior to the year 2003 proved that fretting corrosion in fact occurred with its PROFEMUR® modular necks.

39. Post market surveillance conducted by WRIGHT Defendants from the years 2003 through 2008 proved that fretting corrosion in fact occurred with its PROFEMUR® modular necks.

40. No later than 2003, WRIGHT Defendants recognized that, “metallic particulate debris is approximately an order of magnitude smaller than PE debris, thus even low rates of volumetric wear can lead to large numbers of particles.” Metal-Metal: Metal Ions – A Cause for Concern in Metal Bearings!, presentation by John J. Jacobs, M.D.

41. Testing done by WRIGHT in 2008-2009 proved that fretting corrosion in fact occurred with its PROFEMUR® modular necks.

42. When WRIGHT received complaints about metallosis, adverse local tissue reactions, inflammation, pseudotumors, osteolysis, and bone and tissue necrosis, coupled with early failure of the Wright Total Hip Implant System, it ignored them or blamed the implanting surgeons, and continued promoting and selling the Wright Total Hip Implant System.

43. In various marketing and promotional material published and distributed by WRIGHT from the year 2002, and into the year 2010, and available to WRIGHT's sales representatives and distributors, surgeons, patients, and the general public, WRIGHT made representations, statements, and claims about its CONSERVE® and PROFEMUR® hip product lines that these products were intended for patients who wanted to return to an active lifestyle.

44. In various marketing and promotional material published and distributed by Defendants from approximately the year 2002 and into the year 2008, and available to WRIGHT Defendants made the following representations, statements, claims and guarantees about its PROFEMUR® modular necks:

In summary, the clinical effectiveness and dependability of modular necks has been consistently demonstrated throughout the clinical history of rights Profemur® Modular Necks. Utilized in both primary and revision applications, the current neck design has been successfully employed to improve surgical outcomes with no reported failures. [emphasis added]

[see: Stature™ Modular Hip Reconstruction - Design Rationale - Your stem philosophy. Your next choice. Your crop preference. Wright Medical Technology, Inc. publication MH 179-703, Rev 9.08]

45. In 2001, WRIGHT Defendants made a design change to its PROFEMUR® necks to increase the potential range of motion.

46. In making the 2001 design change to the PROFEMUR® modular necks, WRIGHT Defendants changed the geometry, weight, and mass of the PROFEMUR® modular necks.

47. More than 40,000 of the above-referenced modular necks "designed in 1985," and "successfully implanted in over 50,000 patients," and for which WRIGHT Defendants

claimed, "none of the necks has experienced a clinical failure since their inception," were of the original design that existed prior to the 2001 design change.

48. In fact, prior to the year 2001, Wright Defendants had received notice of clinical failures in the form of fractures of modular necks that had been implanted in patients in Europe.

49. In its initial 510(k) Premarket Notification application to distribute its PROFEMUR® modular necks in the United States, WRIGHT Defendants did not disclose to the FDA that it had notice of clinical failures in the form of modular neck fractures that had been implanted in patients in Europe.

50. Once Wright filed its 510(k) Premarket Notification application to distribute its PROFEMUR® modular necks in the United States, WRIGHT Defendants had a duty to report to the FDA any instances it knew of a clinical failure of its device in patients.

51. Once Wright received permission to distribute its PROFEMUR® modular necks in the United States as a result of its 510(k) Premarket Notification application, WRIGHT Defendants had a duty to report to the FDA any instances it knew of a clinical failure of its device in patients.

52. Prior to January of 2005, Wright knew or received notice of clinical failures in the form of corrosion and fractures of its modular necks that had been implanted in patients in Europe.

53. Prior to April 19, 2005, WRIGHT Defendants did not report to the FDA any of the instances it knew or received notice of that its PROFEMUR® modular neck had clinically failed.

54. On or about April 19, 2005, WRIGHT Defendants first reported to the FDA a PROFEMUR® modular neck clinical failure where the modular neck implanted in a patient had fractured.

55. After receiving notice of the first modular neck fracture, WRIGHT Defendants received notice of additional modular neck clinical failures in the form of fractures of the modular necks. The plaintiff is informed and believes that the fractures were primarily caused by corrosion in the hip.

56. The number of PROFEMUR® modular neck clinical failures in the form of fractures of the modular neck has continued to increase over time, and continues to increase to the present day, now numbering more than 300 such clinical failures.

57. Fractures and corrosion have been reported for both the long and the short versions of the PROFEMUR® modular necks and the rate of failure is excessive compared to other hips on the market.

58. WRIGHT Defendants did not inform U.S. orthopedic surgeons known by WRIGHT Defendants to have implanted its Devices of any reports or concerns about corrosion or fractures of its PROFEMUR® modular necks until a December 1, 2008, "Safety Alert" was sent to certain "medical professionals," which provided, in part, "[W]e have received reports of 43 modular neck failures as of November 21, 2008. Initial investigations have revealed several commonalities in these failures: heavyweight males, long modular necks and patient activities such as heavy lifting and impact sports."

59. At the time WRIGHT Defendants sent the December 1, 2008, Safety Alert, Wright in fact was aware of more than 43 modular neck failures.

60. On or after August 25, 2009, WRIGHT Defendants began distributing in the United States PROFEMUR® modular necks made of a cobalt chrome alloy.

61. PROFEMUR® modular necks distributed in the United States made of cobalt chrome are made in the same twelve sizes, versions and dimensions as the PROFEMUR® Ti6A14V modular necks.

62. Despite the change in materials, the PROFEMUR® cobalt chrome modular necks remain susceptible to micromotion and fretting corrosion at the neck-stem junction, similar to the otherwise identical model of PROFEMUR® Ti6A14V modular necks.

63. Despite the change in materials, the PROFEMUR® cobalt chrome modular necks continue to fail (fracture) at the neck-stem junction from corrosion, cyclic loading and metal fatigue, similar to the otherwise identical model of Pro femur Ti6A14V modular necks.

64. Notwithstanding Defendants' knowledge, until August 2015, Defendants had never directly informed patients in the United States who received the PROFEMUR® modular necks, and have not yet experienced a modular neck fracture, that the PROFEMUR® products have experienced higher than anticipated rates of failure due to corrosion and fracture of the modular neck.

65. Notwithstanding Defendants' knowledge, Defendants have never informed patients in the United States who received the PROFEMUR® modular necks, and have not yet experienced a modular neck fracture, that higher weight and/or higher levels of activity may place patients at an increased risk and rate of failure due to corrosion and fracture of the modular necks.

66. Notwithstanding Defendants' knowledge, Defendants had never directly asked their sales representatives/distributors or surgeons in the United States to directly inform any

surgeons/patients who used/received these modular necks that patients may be placed at an increased risk and rate of failure due to corrosion or fracture of the modular necks.

67. Patient testimonials that have from time to time appeared on the Wright website and were available to Wright sales representatives/distributors, physicians, patients and the public from 2005 to the present, and/or that appeared in printed materials published by Wright from 2005 to the present, have represented that patients who received Wright artificial hips have already returned or are about to return to such activities as running, jogging, snow skiing, water skiing, marathon running, tennis, racquetball, golf, horseback riding, work that involves lifting and moving of heavy objects, active military duty in Iraq, karate, competitive wrestling and competitive 19 motocross racing, among other activities.

68. Patient testimonials that have from time to time appeared on the Wright website, and in printed materials published by Wright from 2005 to the present, have been from men who received the Devices and weighed in excess of 250 pounds.

69. On September 28, 2015, the FDA issued a Class 1 hip replacement recall of the PROFEMUR® Long Cobalt Chrome neck component, and, advised patients to seek immediate medical treatment if they experience a sudden onset of severe pain in their post-operative hip.

70. In a "webinar" produced by WRIGHT Defendants and intended to be viewed by orthopedic surgeons, Brad Penenberg, M.D., an orthopedic surgeon WRIGHT Defendants paid to train other orthopedic surgeons to use a technique for implantation of the Wright Hip System replacement surgery, and that they may return to activities and lifestyles that included tennis, horseback riding and snow skiing.

71. As a result of Defendants' aggressive and misleading marketing, and failure to acknowledge and warn surgeons, patients and the public about known problems with metal-

on-metal hip replacements in general and the Wright Total Hip Implant System in particular, Plaintiff and many others, received defective and unreasonably dangerous Wright Total Hip Implant Systems. Plaintiff, like many other patients who received these defective medical devices, has endured unnecessary pain and suffering, debilitating lack of mobility, loosening through osteolysis, inflammation causing damage or death to tissue and bone around the implant, metallosis, toxicity, and a subsequent more difficult revision surgery to replace the defective Wright Total Hip Implant System, giving rise to additional pain and suffering, prolonged recovery time, and an increased risk of complications and death from surgery.

**WRIGHT MEDICAL “PHASES OUT” ITS TITANIUM MODULAR NECKS  
AND REPLACES THE TITANIUM WITH COBALT CHROMIUM**

72. After realizing that the PROFEMUR® long titanium necks would catastrophically fail the ASTM F 2068-03 standard, Wright Medical decided to phase out the PROFEMUR® Modular Necks made with titanium and replace them with a cobalt-chrome alloy.

73. On or after August 25, 2009, WRIGHT began distributing in the United States PROFEMUR® modular necks made of a CoCr alloy.

74. On or after August 25, 2009, Wright Medical changed PROFEMUR® Modular Necks to the cobalt-chrome alloy, yet, issued no warnings or modifications.

75. While Defendant WRIGHT wanted to market its PROFEMUR® Neck in the United States, it did not want to endure the long and expensive FDA approval process. Instead, WRIGHT exploited a loophole in FDA regulations that would allow its device to enter the United States market without proper testing or approval. WRIGHT represented that the PROFEMUR® Neck design was substantially equivalent to other hip replacement products already on the market.



76. While representing to the FDA that the PROFEMUR® Neck was "substantially equivalent" to other hip replacement products, WRIGHT omitted the PROFEMUR® System's critical distinguishing features.

77. PROFEMUR® Modular Necks distributed in the United States made of cobalt chrome are made in the same six long versions, and the same six short versions, as the six long and six short versions of the PROFEMUR® Titanium Modular Necks.

78. PROFEMUR® Modular Necks distributed in the United States made of cobalt chrome have the same dimensions as the trunnion, and at the oblong taper, as PROFEMUR® Titanium Modular Necks, making them compatible for assembly with the same Wright Medical femoral heads and hips stems that the PROFEMUR® Titanium Modular Necks were compatible with.

#### **DEFECTIVE METAL-ON-METAL DESIGN**

79. Defendants have known for years that implementation of the CONSERVE® and PROFEMUR® Systems of the Wright Total Hip System results in metallosis, biological toxicity, and an increased risk for early and excessive premature failures of the Wright Total Hip System.

80. Implantation of the CONSERVE® System in congruence with the PROFEMUR® System results in the release of high levels of toxic metal ions into hip implant patients' tissues and bloodstreams. Particles released by friction of the metal- on-metal surfaces also results in metallosis, tissue death, and tumor growth. This friction wear is especially pronounced in the early "wear in" period, especially on the leading edge of the metal acetabular Cup. In the hip implant industry, this is commonly referred to as "edge wear" or "edge loading."

81. The Wright Total Hip System is defective because proper and successful surgical placement is exceedingly difficult for even experienced and competent surgeons to accomplish in implanting the Wright Total Hip System in patients.

82. Once the body is exposed to the CONSERVE® and PROFEMUR® application of the Wright Total Hip System and absorbs the toxic metallic ions and particulate debris created by friction of the metal-on-metal, inflammation occurs which leads to severe pain, infection, death of the surrounding tissue, bone loss, and the potential for tumors to develop. Since 2006, Defendants have had actual knowledge that the CONSERVE® System would fail early due to metal debris, thereby giving rise to unnecessary pain and suffering, debilitation, and the need for revision surgery to replace the defective devices with the attendant risk of complications and death from such further implant revision surgery in patients, including Plaintiff.

83. The fact that the Wright Total Hip System with the CONSERVE® and PROFEMUR® Systems fail prematurely and thereby gives rise to unnecessary pain and suffering, debilitation, and the need for revision surgery for implanted patients is a material fact.

84. Defendants failed to disclose this material fact to consumers, including PLAINTIFF MILLER and plaintiff's physician.

#### **CONSERVE® RELIANCE**

85. Instead, Defendants took affirmative steps to prevent physicians and consumers, including, but not limited to, PLAINTIFF MILLER, from learning of this material fact, while aggressively marketing the Wright Total Hip System and CONSERVE® Cup as safe and effective for use in hip replacement surgeries. This concealment was made with the intent to induce Plaintiff, as well as other patients and physicians, to purchase the Wright Total Hip

System and the CONSERVE® Cup and to prevent patients from discovering they were implanted with a defective device and from filing lawsuits seeking damages.

86. Plaintiff and plaintiff's physicians would have been able to discover the cause of plaintiff's pain and disability or defects in the Wright Total Hip System earlier, but for the fact that Defendants actively concealed these facts from physicians, patients, and Plaintiff, which led to a delay in discovery as well as unnecessary suffering for Plaintiff.

87. In reliance on Defendants' fraudulent concealment of material fact, Plaintiff's implanting surgeon selected, and PLAINTIFF MILLER purchased the Wright Total Hip System so that plaintiff's surgeon could surgically implant the Wright Total Hip System into plaintiff's body. Had PLAINTIFF MILLER's surgeon known that the Wright Total Hip System would fail early, thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for revision surgery to replace the Wright Total Hip System with the attendant risk of complications and death from such further surgery, Plaintiff's implanting surgeon would not have selected the Wright Total Hip System for implantation into Plaintiff. Had Plaintiff known that the Wright Total Hip System would fail early, thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for revision surgery to replace the Wright Total Hip System with the attendant risk of complications and death from such further surgery, Plaintiff would not have purchased the Wright Total Hip System.

88. Defendants made representations, affirmations of fact, and/or promises through their advertisements, labeling, detailing, marketing, and/or promotion of the Wright Total Hip System to healthcare professionals, the FDA, Plaintiff, and the public by representing that the induce patients and surgeons to purchase or use the Wright Total Hip System with the CONSERVE® Cup.

89. These representations, affirmations, and/or promises regarding the Wright Total Hip System were false. These representations, affirmations, and/or promises also constitute express warranties that the Wright Total Hip System with the CONSERVE® Cup component conform to those representations.

90. PLAINTIFF MILLER was in privity with WRIGHT through plaintiff's surgeon, acting as an agent, and relied on WRIGHT's express warranties and/or representations in choosing to purchase the Wright Total Hip System with CONSERVE® Cup component.

91. Defendants utilized misrepresentations that contradicted their own knowledge regarding activity levels and metal ions to drive sales of the CONSERVE® System. Despite knowing that increased activity would lead to increased wear, Defendants directed their marketing (via websites, journal ads, brochures, pamphlets, patient testimonials, endorsements, newspaper articles and other PR) aimed at surgeons and younger, more active consumers who wanted to return to the following strenuous physical activities, including but not limited to:

- a. Surfing;
- b. Yoga;
- c. Skiing;
- d. Martial Arts, including competition levels;
- e. Hockey;
- f. Ice skating;
- g. Motorcycling;
- h. Horseback rides;
- i. Tennis;
- j. Golf;
- k. Soccer;
- l. Football;
- m. Mountain climbing;
- n. Running, including marathons and triathlons;
- o. Hiking;
- p. Biking, including trail riding;
- q. Swimming;
- r. Racquetball;

- s. Active military duty;
- t. Competitive wrestling; and
- u. Kayaking.

92. Representative of these ads include:



93. No later than 2003, WRIGHT recognized that, “metallic particulate debris is approximately an order of magnitude smaller than PE debris, thus even low rates of volumetric wear can lead to large numbers of particles.” *Metal-Metal: Metal Ions – A Cause for Concern in Metal Bearings!*, presentation by John J. Jacobs, M.D.

94. Before, during and since WRIGHT designed developed, manufactured, marketed, and sold its CONSERVE® Systems, WRIGHT knew patients with CONSERVE® metal on metal hip implants exhibited 10 times higher concentrations of metal ions compared to patients with metal on poly hip implants.

95. When marketing the CONSERVE® Systems, WRIGHT worked to overcome a critical concern for metal-on-metal hip devices, i.e., metal ion release. Thus, as part of its

marketing strategy to “de-criminalize metal ions” and drive sales, WRIGHT instructed its sales personnel, contrary to its own knowledge, that the effects of metal ion release are known and have been demonstrated to be safe and had surgeon consultants promote that its A-Class metal reduced wear and generated fewer metal ions.

96. WRIGHT promoted the decriminalization of metal ions through consulting surgeon Key Opinion Leaders’ (“KOL”) presentations to orthopaedic groups, paid-for scientific data publications, celebrity endorsements, and sales representative training, among other avenues.

97. Defendants utilized taglines such as “Reduced Wear, Increased Longevity,” “A-Class Never Compromise,” and “A Hip for Life” in marketing its A-Class BFH technology with the Conserve Total Hip Device.

98. Defendants have never reported the CONSERVE® System’s high failure rates to surgeons, to patients with implanted CONSERVE® Systems, or to the public.

99. Upon information and belief, WRIGHT received complaints and reports of unacceptable failure rates of its CONSERVE® Systems from Brad Penenberg, M.D., a Wright KOL, consultant, Fab Four member, Peer-to-Peer trainer, premier Los Angeles surgeon and CONSERVE® royalty recipient, who concluded the CONSERVE® was not a successful product and stopped using them because of problems he experienced with the CONSERVE® starting in 2007.

100. Dr. Penenberg’s findings are especially relevant to Plaintiff’s case because Plaintiff’s implanting surgeon, Dr. Vincent Fowble, stopped using CONSERVE® in 2011 because of the high rate of revisions he saw in his patients. Had WRIGHT disclosed to Dr. Vincent Fowble the high revision rate that Dr. Penenberg saw in his 700 CONSERVE® implantations, he would have made the decision to stop using the Wright Total Hip System

before he implanted the CONSERVE® in Plaintiff's hip in April 2010 and again in November 2010.

101. Defendants knew their representations were false or made these representations recklessly, knowing that they lacked sufficient knowledge upon which to base such representations.

102. Defendants made these representations for the purpose of inducing orthopaedic surgeons, including Dr. Satereanos who was Plaintiff's implanting surgeon, and patients like Plaintiff to act upon the representations and select the CONSERVE® as part of the Wright Hip Implant System for implantation.

103. WRIGHT advertised on its website and in its product brochures that were distributed to physicians and patients as early as September of 2004 that Wright's Total Hip System with CONSERVE® Cup was designed to be an improvement over the metal-on-polyethylene implants because the metal-on-metal design would reduce the amount of wear particles.

104. In particular, Defendants' advertisements, and representations, included this statement:

Despite improvements in the manufacturing, processing, and sterilization of polyethylene, wear related problems still exist in modern total hip arthroplasty. To address this problem, the CONSERVE® Total Hip System has eliminated polyethylene from the design altogether. The result is a one-piece, highly super finished metal-on-metal design, which provides significantly less wear particles than the conventional total hip replacement.

105. Defendants' advertisements and representations also included misleading information that would lead both patients and their surgeons to believe there would only be a minimal amount of wear debris generated from the CONSERVE® Cup in that the amount of

wear debris would be substantially less than that associated with ceramic-on-polyethylene or cobalt chrome- on-polyethylene implant designs.

106. Plaintiff's physicians communicated Defendants' representations to plaintiff. These representations about the extended durability of the Wright Total Hip System with CONSERVE® Cup led Plaintiff and plaintiff's surgeon to believe that the Wright Total Hip System with a CONSERVE® Cup component would last longer than the approximate 15 to 20 years that a conventional hip implant would last.

107. Defendants knew that the Wright Total Hip System with CONSERVE® Cup would fail prematurely due to metal debris, thereby giving rise to unnecessary pain and suffering for patients, debilitation, and the need for revision surgery to replace the defective Wright Total Hip System, yet, at the same time, Defendants were representing to patients and surgeons, including PLAINTIFF MILLER, that the Wright Total Hip System with CONSERVE® Cup component has fewer potential safety risks than other implant models and designs.

### **CLAIMS FOR RELIEF**

#### **FIRST CAUSE OF ACTION**

#### **STRICT PRODUCTS LIABILITY FAILURE TO WARN**

#### **(As Against All Defendants)**

108. Plaintiff incorporates by reference the factual background set forth in above.

109. At all times relevant herein, Defendants were engaged in the design, development, testing, manufacturing, distribution, marketing, promoting and/or sale of the Wright Total Hip System.



110. Defendants designed, manufactured, assembled, distributed, marketed, promoted and/or sold the Wright Total Hip System to medical professionals and patients knowing that they would then be implanted in patients in need of hip prosthesis.

111. Defendants distributed and sold the Wright Total Hip System in their original form of manufacture, which included the defects described herein.

112. The Wright Total Hip System was expected to and did reach Plaintiff and plaintiff's implanting surgeon in the State of Oregon without substantial change or adjustment in its condition as manufactured and sold by Defendants.

113. The Wright Total Hip System designed, developed, tested, manufactured, distributed, promoted, marketed and/or sold or otherwise placed into the stream of commerce by Defendants were in a dangerous and defective condition and posed a threat to any user or consumer of the Wright Total Hip System.

114. At all times relevant hereto, Plaintiff was a person the Defendants should have considered to be subject to the harm caused by the defective nature of the Wright Total Hip System.

115. The Wright Total Hip System was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert the medical community and patients, including Plaintiff and plaintiff's healthcare providers, to the dangerous risks associated with the Wright Total Hip System when used for its intended and reasonable foreseeable purpose. The dangers and risks included, but were not limited to, a tendency to (a) detach, disconnect and/or loosen from a patient's acetabulum; (b) generate dangerous and harmful metal debris in the patient's body; (c) corrode; (d) cause pain; (e) inhibit mobility and (f) require revision surgery.

116. At all times relevant hereto, Plaintiff and plaintiff's healthcare providers used the Wright Total Hip System for its intended or reasonably foreseeable purpose.

117. Plaintiff and plaintiff's healthcare providers could have discovered no defect in the Wright Total Hip System through exercising due care.

118. Defendants knew or should have known, by the use of scientific knowledge available before, at and after the time of manufacture, distribution and sale of the Wright Total Hip System, of potential risks and side effects associated with the Wright Total Hip System. Defendants knew or should have known of the defective condition, characteristics, and risks associated with the said product, as previously set forth herein.

119. The warnings and instructions provided with the Wright Total Hip System by Defendants did not adequately warn of the potential risks and side effects of the Wright Total Hip System, which risks were known or scientifically knowable to Defendants.

120. Defendants had a continuing duty to warn the medical community and public, including Plaintiff and plaintiff's healthcare providers, of the potential risks and increased failure rate associated with the Wright Total Hip System.

121. Defendants had a duty to warn implanting surgeons such as plaintiff's surgeon, and patients such as Plaintiff, and Defendants breached their duty in that they failed to provide adequate and timely warnings or instructions regarding their Wright Total Hip System and their known defects.

122. Defendants, furthermore, breached their duty to warn at pre-surgery and/or post- surgery by (a) failing to adequately communicate the warning to the ultimate users, i.e., Plaintiff and/or plaintiff's implanting physician; and/or (b) by failing to provide an adequate warning of the Wright Total Hip System's potential risks.

123. Adequate effort to communicate a warning to the ultimate uses were not made by Defendants and, to the extent a warning was communicated by Defendants, the warning was inadequate.

124. Plaintiff used the Wright Total Hip System for its intended purpose, i.e., hip replacement.

125. Plaintiff could not have discovered any defect in the Wright Total Hip System through the exercise of due care.

126. Defendants, as designers, manufacturers, distributors, promoters, marketers and/ or sellers of medical devices are held to the level of knowledge of experts in their field.

127. Neither Plaintiff nor plaintiff's implanting physician had substantially the same knowledge about the Wright Total Hip System as Defendants.

128. As a direct, legal and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff has sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as set forth herein.

129. Defendants' failure to adequately warn of the potential risks and side effects of the Wright Total Hip System was a substantial factor in causing Plaintiff's injuries as set forth above.

**SECOND CAUSE OF ACTION**  
**STRICT PRODUCTS LIABILITY DEFECTIVE DESIGN**  
**(As Against all Defendants)**

130. Plaintiff incorporates by reference the factual background set forth in above.

131. The Wright Defendants had a duty to design and manufacture, and all Defendants had a duty to place into the stream of commerce, distribute, market, promote and sell, the Wright Total Hip System so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

132. At all times relevant hereto, Defendants designed, manufactured, distributed, sold, marketed and/or promoted the Wright Total Hip System, including components implanted in Plaintiff on May 1, 2006.

133. The Wright Defendants did in fact design and manufacture, while all Defendants were engaged in selling, distributing, supplying and/or promoting the Wright Total Hip System to Plaintiff and plaintiff's implanting physician. Defendants expected the Wright Total Hip System they were selling, distributing, supplying, manufacturing and/or promoting to reach, and it did in fact reach, implanting physicians and consumers in the State of Oregon, including Plaintiff and plaintiff's implanting physician, without substantial change in the condition.

134. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers used the Wright Total Hip System for its intended or reasonably foreseeable purpose.

135. At all times relevant hereto, the Wright Total Hip System was dangerous, unsafe and defective in manufacture. Such defects included, but were not limited to, a tendency to (a) detach, disconnect and/or loosen from a patient's acetabulum and femur; (b) generate dangerous and harmful metal debris in the patient's body; (c) corrode; (d) cause pain; (e) inhibit mobility; (f) require revision surgery.

136. Defendants knew or should have known of the unreasonably dangerous and serious risks associated with the design of the Wright Total Hip System. Such risks were

scientifically knowable to Defendants. However, Defendants performed inadequate evaluation and testing of the Wright Total Hip System design.

137. The Wright Total Hip System, manufactured and supplied by the WRIGHT Defendants and distributed, marketed, promoted and sold by all Defendants, were, therefore, defective in design or formulation in that, when they left the hands of Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

138. As a direct, legal, proximate and producing result of the defective manufacture of the Wright Total Hip System implanted in Plaintiff, Plaintiff sustained injuries as set forth above.

139. Defendants' dangerous design and failure to adequately test the safety of the Wright Total Hip System was a substantial factor in causing Plaintiff's injuries as set forth above.

**THIRD CAUSE OF ACTION**  
**NEGLIGENCE**  
**(As Against All Defendants)**

140. Plaintiff incorporates by reference the factual background set forth in herein.

141. At all times relevant hereto, Defendants designed, manufactured, distributed, sold, marketed and/or promoted the Wright Total Hip System for implantation into customers, such as Plaintiff, by physicians, surgeons and health care providers in the United States.

142. At all times relevant hereto, Defendants knew or should have known that

the novel design of the Wright Total Hip System necessitated clinical trials and other pre-marketing evaluations of risk and efficacy. Such testing would have revealed the increased risk of failure and complications associated with the Wright Total Hip System. A reasonable manufacturer under the same or similar circumstances would have conducted additional testing and evaluation of the Wright Total Hip System's safety and performance prior to placing the Wright Total Hip System into the stream of commerce.

143. At all times relevant hereto, Defendants knew or should have known of the serious complications and high failure rate associated with the Wright Total Hip System. Despite receiving hundreds of reports of serious complications from healthcare providers, Defendants chose (1) not to perform any additional testing of the Wright Total Hip System; (2) not investigate other potential causes of the reported complications; (3) suspend sales or distribution; or (4) warn physicians and patients of the propensity of the Wright Total Hip System to detach, disconnect and/or loosen from a patient's acetabulum; generate dangerous and harmful metal debris in the patient's body; cause pain; inhibit mobility; and/or require revision surgery.

144. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, warning, marketing, promotions and distribution of the Wright Total Hip System in that they knew or should have known that these products caused significant bodily harm and were not safe for use by consumers, and/or through failure to comply with federal requirements.

145. The WRIGHT Defendants were negligent in designing and manufacturing the CONSERVE® System such that it caused metal-on-metal wear between the femoral and acetabular components of the Wright Total Hip System, increased metallic corrosion, and

caused serious side effects, including; but not limited to, severe pain and disability, metallosis, synovitis, bone loss, tissue necrosis, premature failure, the need for revision surgery, and death.

146. The WRIGHT Defendants were negligent in designing and manufacturing the PROFEMUR® System such that it caused metal wear and mixing of the metals between the modular neck and femoral stem of the Wright Total Hip System, increased metallic corrosion, and caused serious side effects, including; but not limited to, severe pain and disability, metallosis, synovitis, bone loss, tissue necrosis, premature failure, the need for revision surgery, and death.

147. Prior to and at the time that plaintiff's physician performed implantation surgery for Plaintiff on May 1, 2006, Defendants knew or should have known that the CONSERVE® and PROFEMUR® Systems of the Wright Total Hip System were defective for the reasons described herein, and Defendants had the opportunity and duty to warn plaintiff's physician and Plaintiff of the defective nature of the CONSERVE® and PROFEMUR® Systems.

148. Defendants' conduct, as described above, including, but not limited to, their failure to adequately test and warn, as well as their continued marketing and distribution of the Wright Total Hip System when they knew or should have known of the serious health risks these devices created and/or the failure to comply with federal requirements, was and is negligent.

149. As a direct, legal, proximate and producing result of the Defendants' negligent design, testing, manufacturing, marketing selling and promoting the Wright Total Hip System, Plaintiff sustained injuries as set forth above.

150. Defendants' negligent design, testing, manufacturing, marketing, selling

and promoting of the Wright Total Hip System implanted in Plaintiff were a substantial factor in Plaintiff's injuries as set forth above.

**FOURTH CAUSE OF ACTION**  
**NEGLIGENT MISREPRESENTATION**  
**(As Against All Defendants)**

151. Plaintiff incorporates by reference the factual background set forth herein.

152. All Defendants, knowingly and intentionally made material, false and misleading representations to Plaintiff, plaintiff's physicians, and to the public that the Defendants' CONSERVE® and PROFEMUR® Hip Systems had been adequately tested and were safe and effective.

153. Defendants' representations to Plaintiff's physician, as referenced in previous paragraphs of this complaint, include, but are not limited to, the following:

- a. The CONSERVE® hip system is a life-long solution for young, active patient's hip problems.
- b. The CONSERVE® hip system should last for fifteen to twenty (15-20) years in patients like Plaintiff.
- c. No later than 2003, WRIGHT recognized that, "metallic particulate debris is approximately an order of magnitude smaller than PE debris, thus even low rates of volumetric wear can lead to large numbers of particles."
- d. Defendants utilized taglines such as "Reduced Wear, Increased Longevity," "A-Class Never Compromise," and "A Hip for Life" in marketing its A-Class BFH technology with the Conserve Total Hip Device.
- e. Defendants' advertisements and representations for the Wright Total Hip System, including the CONSERVE® included "significantly less wear particles than the conventional total hip replacement".



- f. Defendants' advertisements and representations also included misleading information that would lead both patients and their surgeons to believe there would only be a *minimal amount of wear debris generated* from the CONSERVE® Cup in that the amount of wear debris would be substantially less than that associated with ceramic-on-polyethylene or cobalt chrome- on-polyethylene implant designs.

154. Defendants' representations, as identified above, were in fact false.

155. At the time Defendants made these representations to Plaintiff's physician, Defendants knew, or should have known, that:

- a. The CONSERVE® hip system would not last for 15 - 20 years.
- b. The CONSERVE® had a substantially higher amount of metallic wear debris than disclosed and/or represented by Defendants.
- c. The CONSERVE® was not safe and effective.

156. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, Plaintiff's physician, and the public and medical community in general, and were made with the intent of inducing Plaintiff's physician, Plaintiff, and the medical and healthcare community in particular, to recommend, dispense, and/or purchase the Wright Hip System, all of which is evidence of callous, reckless, and willful disregard for the health, safety, and welfare of patients, including Plaintiff.

157. Plaintiff's physician reasonably relied on the specific allegations made by DEFENDANTS, the manufacture, seller and distributors of the produced implanted in Plaintiff, which representations are described in previous paragraphs of this complaint.

158. Neither Plaintiff nor Plaintiff's physician had reason to doubt the truth of representations made by Defendants about its CONSERVE® and PROFEMUR® Systems.

159. In justifiable reliance upon said representations, Plaintiff and/or plaintiff's medical providers were induced to and did have implanted the CONSERVE® and

PROFEMUR® Hip Systems for use as a total hip arthroplasty, thereby causing Plaintiff to suffer severe personal injuries.

160. Had Defendants informed Plaintiff and/or plaintiff's medical providers that their representations were false, Plaintiff, and/or plaintiff's medical providers, would not have selected and purchased the CONSERVE® and PROFEMUR® Hip Systems.

161. As a direct and proximate result of Defendants' fraudulent negligent misrepresentations and/or omissions, Plaintiff suffered harm, damages, and economic loss.

162. In the exercise of reasonable care, Defendants should have known that the Wright Total Hip System failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet they negligently misrepresented to Plaintiff and/or plaintiff's physician that their device was safe and met all applicable design and manufacturing requirements.

163. Defendants made misrepresentations and material omissions in their marketing, advertisements, promotions and labeling concerning these products for use in patients such as Plaintiff.

164. Plaintiff and/or plaintiff's physician justifiably relied to their detriment upon Defendants' misrepresentations and omissions in their marketing, advertisements, promotions and labeling concerning these products.

165. Plaintiff and/or plaintiff's physician justifiably relied upon Defendants' representations that the Wright Total Hip System were safe for use in persons such as Plaintiff.

166. As a direct and proximate result of Defendants' negligent misrepresentations and omissions of the Wright Total Hip System, Plaintiff used the CONSERVE® and PROFEMUR® systems and has suffered serious physical injury, harm,

damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

167. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff BEVERLY J. MILLER has suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

**FIFTH CAUSE OF ACTION**  
**LOSS OF CONSORTIUM**

168. Plaintiffs adopt and re-allege the allegations contained in the above paragraphs as if set forth fully herein.

169. Plaintiff Mrs. Miller was and still is the lawful wife of Plaintiff Dwyn E. Miller.

170. As a direct and proximate result of Defendants' defective Product and tortious conduct, and as a result of the injuries and damages to Plaintiff Miller arising therefrom, Plaintiff Dwyn E. Miller has been deprived of the love, companionship, comfort, affection, society, solace or moral support, protection, loss of enjoyment of sexual relations, and loss of physical assistance in the operation and maintenance of the home, of his wife, Beverly Miller, and has thereby sustained and will continue to sustain damages.

171. The damages sustained by Plaintiff Dwyn E. Miller are a direct and consequential result of the action or inaction of negligence and palpable negligence of the Wright Defendants.

172. Plaintiff Dwyn E. Miller is entitled to recover damages for his loss of consortium in an amount to be proven at trial.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs demand judgment against the Defendants, and each of them, in an amount which exceeds the jurisdictional limits of all lower courts, together with interests, costs, and disbursements of this action, including damages including, but not limited to:

(a) for special damages, to include past and future medical and incidental expenses, according to proof;

(b) for past and future loss of earnings and/or earning capacity, according to proof;

(c) for past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;

(d) for Plaintiff Dwyn E. Miller damages for loss of consortium;

(e) for pre-judgment and post-judgment interest;

(f) for the costs of this action, including reasonable attorneys' fees; and

(g) granting any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiffs hereby request a trial by jury of all issues triable by jury.

November 24, 2020.

**JOHNSON JOHNSON LUCAS & MIDDLETON, P.C.**

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